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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,999	10/28/2003	Ilya Davydov	GRT/4504-2	4116
23117 7590 09/30/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
DESAI, ANAND U				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
09/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/693,999

**Applicant(s)**

DAVYDOV ET AL.

**Examiner**

ANAND U. DESAI, Ph.D.

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-8, 17 and 57-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 4, 17 and 57-64 is/are allowed.
- 6) ☒ Claim(s) 5-8 and 65-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to the amendment filed on June 30, 2008.
2. Claims 3-8, 17, and 57-66 are currently pending and are under examination.

### **Withdrawal of Rejections**

3. The rejection of claims 3, 4, 17, and 57-64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.
4. The rejection of claims 3, 4, 17, and 57-64 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the amendment to delete the reference to a derivative and the remarks.

### **Pending Rejections**

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 5-8 and 65-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 5 recites the limitation "said fragment or derivative thereof" in part A) 2<sup>nd</sup> line. There is insufficient antecedent basis for this limitation in the claim. The word derivative has been deleted in step (b) of the claim.

8. Claim 65 recites the limitation "said fragment or derivative comprises" in part A) (i) 9<sup>th</sup> line. There is insufficient antecedent basis for this limitation in the claim. The word derivative has been deleted in step A) (i) 3<sup>rd</sup> line of the claim.
9. Claims 6-8 and 66 are rejected for depending on a rejected base claim.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, Written Description***

10. Claims 5-8, and 65-66 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5-8 and 65-66 are rejected under 35 U.S.C. 1<sup>st</sup> paragraph, Written Description because the disclosure does not sufficiently describe the structure of the conjugate of derivatives. The formation of a conjugate by N-end rule ubiquitylation does not sufficiently describe the conjugate structure because the enzymes involved in forming the conjugates are unknown and it is not clearly described as to how the conjugation occurs between the two molecules. What is the structure of the conjugate? Which internal lysine residue on the derivative is covalently linked with ubiquitin? The person having ordinary skill in the art cannot envision the structure of the conjugate currently claimed.

**Response to Remarks**

Applicants traverse the rejection because the specification teaches a representative number of species of the claimed genus. The structure of the conjugate after N-end rule

ubiquitylation is also clear. Applicant's arguments filed June 30, 2008 have been fully considered but they are not persuasive. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. The person having ordinary skill in the art cannot envision the structure of the conjugate currently claimed with any derivative protein. Suggest amending the claims to remove reference to the derivatives as currently pending.

### ***Claim Objections***

11. Claim 3 is objected to because of the following informalities:
12. Suggest spelling out the respective proteins and placing the abbreviations in parenthesis at the first occurrence in the claims.

Appropriate correction is required.

### ***Conclusion***

13. Claims 3, 4, 17, and 57-64 are allowable.
14. Claims 5-8 and 65-66 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI, Ph.D. whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 26, 2008  
/ANAND U DESAI, Ph.D./  
Examiner, Art Unit 1656